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D1 X the influent gas and the effluent gas;

said second conduit has a length such that the gas flow alarm, when in use by a recipient of the effluent gas, is proximate to the recipient of the effluent gas.

Cancel Claim 2 without prejudice.

Please amend Claim 3 as follows:

D2 3. The personal gas supply delivery system according to claim 1 wherein the gas flow alarm is set to alert a subject desiring to receive the effluent gas when the pressure of the influent gas and the effluent gas has met at least one predetermined setting.

Please amend Claim 5 as follows:

D3 5. The personal gas supply delivery system according to claim 1 wherein the gas flow alarm is set to alert a subject desiring to receive the effluent gas when the pressure of the influent gas and the effluent gas has met at least one predetermined setting and the alerting of the subject is by visible light.

[Please amend Claim 6 as follows:]

D4 6. The personal gas supply delivery system according to claim 1 wherein the gas flow alarm is set to alert a subject desiring to receive the effluent gas when the pressure of the influent gas and the effluent gas has met at least one predetermined setting and the alerting of the subject is audible.

Please amend Claim 11 as follows:

11. A personal gas supply delivery system comprising:  
a moisturizing vessel, for when in use, having the capability to contain a liquid  
to provide a source of moisture to increase the amount of moisture  
in a gas passing through the liquid,  
said moisturizing vessel having a first opening for receiving an influent gas,  
said moisturizing vessel having a second opening for an effluent gas,  
a first conduit connected with said second opening, said first conduit for when  
in use, for receiving the effluent gas,  
a gas flow alarm connected with said first conduit, and

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D4  
D4  
Cont

a second conduit connected with said gas flow alarm, said second conduit in fluid communication with said first conduit, said second conduit is unitary and connecting with a binary nasal cannula; said gas flow alarm for determining an instantaneous difference in the pressure or volume of the influent gas per unit of time and the volume of the effluent gas per unit of time.

Cancel Claim 12 without prejudice.

Please amend Claim 15 as follows:

D5

15. The personal gas supply delivery system according to claim 11 wherein the gas flow alarm is set to alert a subject desiring to receive the effluent gas when the volume of the influent gas and the effluent gas has met has met at least one predetermined setting and the alerting of the subject is by visible light.

Please amend Claim 16 as follows:

D5

16. The personal gas supply delivery system according to claim 11 wherein the gas flow alarm is set to alert a subject desiring to receive the effluent gas when the volume of the influent gas and the effluent gas has met has met at least one predetermined setting and the alerting of the subject is audible.

Please amend Claim 19 as follows:

D6

19. The personal gas supply delivery system according to claim 18 wherein the gas flow alarm is set to alert a second person by means of a transmitter and a receiver that the pressure or the volume per unit of time of the influent gas and the effluent gas has met at least one predetermined setting.

Please amend Claim 21 as follows:

D7

21. (Twice Amended) A personal gas supply delivery alarm system comprising:

a first conduit, for when in use receiving a supply of a gas at a first pressure from a first gas supply line,

said first conduit connected with a battery powered gas flow alarm, said gas flow alarm for when in use for determining an instantaneous difference in the

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pressure or volume of the gas per unit of time and the volume of the [effluent] gas per unit of time,

*D  
Cont*  
a second conduit connected with said gas flow alarm, for when in use receiving the supply of gas through said gas flow alarm,

said first conduit having a first connector, for when in use providing a detachable airtight seal with a compatible connector on the gas supply line, said first connector located distally from said gas flow alarm, and

said second conduit having a second connector, for when in use providing a detachable airtight seal with a compatible connector on a second gas supply line, said second connector located distally from said gas flow alarm,

said second gas supply line terminating in a nasal cannula.

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#### Discussion of the Interview

The representative of the applicants, Mr. Joseph Coury, and the undersigned counsel, thank Examiners Patel, Lo, and Lewis for the interview of September 16, 2002.

The applicant has further revised the claims as discussed below. The general nature of the amendment is to clarify and claim the device as being within the control of a person desiring to be a recipient of an uninterrupted flow of the medical gas. The term differential has also been revised to meet one of the concerns expressed during the interview.

#### Discussion of the 35 USC 102 Rejections

The Examiner has rejected claims 1, 3, 4, 5, 6, 7, 11, 13, 14, 15, 17, 21, 23, 24, 25, 26, and 29 (renumbered 28) based on Bird United States Patent 5,165,398 (hereinafter the Bird patent).

Prior to discussing the nature of the rejections the applicant feels that a brief review of the claimed invention will be the Examiner in determining the differences between that which is claimed and the cited art.

The present invention deals with an uncomplicated system for providing a gas such as oxygen to a person in need of such gas. A difficulty that is been found with such oxygen delivery systems, particularly those that are portable or located in the

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home of the user, is reliability. Portable oxygen generation systems use a thin hose to deliver the oxygen from a tank or oxygen separator to the user. The hose may become crimped or cut at any point thus depriving the user of needed oxygen who may be of diminished capacity to determine if the oxygen is being delivered.

Further, as the oxygen supply to a user needs moisture to prevent over drying of the user's airways it is desirable to moisturize the oxygen. The oxygen which is moisturized is typically accomplished with a vessel containing water through which the oxygen is bubbled. The moist oxygen is then supplied to the user through another thin hose, and in the case of present invention, the thin hose is connected with nasal cannula.

The use of a vessel presents a significant possibility for the loss of the entire supply of oxygen. Typically, a bottle used to moisturize the oxygen will be a plastic screw top bottle and the top the bottle from which the oxygen is received and moisturized oxygen dispensed will also be plastic. A significant potential exists for the bottle to be damaged at the threads through repeated usage. Another factor in the use of the bottle is where the screws in the cap are not aligned properly with the threads in the bottle thus providing direct leakage of the oxygen in which case the subject does not receive the oxygen. As previously noted, the user of the oxygen may be of diminished capacity and will not know that the flow of oxygen is interrupted.

The present invention provides an alarm in direct proximity to the user of the oxygen. The alarm is typically portable or generates a light to permit the user or another in the vicinity to be alerted to the lack of oxygen flow. The alarm system of invention provides a reliable system for a user of oxygen in a portable or home setting, or for that matter in a hospital, to know on a reliable basis that the oxygen is being supplied to the user.

In contrast the flow of gas in the present invention is from the hollow flexible tubing 14 through the gas flow alarm 20 and to the user through nasal fittings 102 and 104.

The Examiner has rejected claim 1 based on the Bird patent as lacking novelty.

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A difference between the Bird patent and claim 1 of the present invention is that the second conduit has a length such that the gas flow alarm, when used by a person desiring to be a recipient of an uninterrupted flow of the medical gas (effluent gas), is proximate to the recipient of the effluent gas. The device to be useful in a home or other setting must permit the person receiving the gas to understand that the gas flow has been interrupted. No such teaching is found in the Bird patent.

Therefore, claim 1 is novel over the Bird patent. Thus, the rejections based on the Bird patent regarding claim 1 and all claims dependent from claim 1 should be removed.

Claim 2 recites that the gas distributive device is a nasal cannula. The Bird patent, at column 6, line 8 teaches an endotracheal tube not nasal cannula. A person utilizing an endotracheal tube is not in a position to take action if the gas flow is interrupted thus the Bird patent teaches nothing regarding a system where the person receiving the medical gas can take action by being so alerted.

The applicant cannot locate in the Bird patent a teaching that a gas flow alarm is set to alert a subject receiving the effluent gas by any means. Therefore, it is believed that claim 4 is novel over the Bird patent. Thus, the rejection to claim 4 over the Bird patent should be removed and such as requested.

The applicant's claim 5 requires, in part, that the subject is alerted to a gas flow problem by a visible light. As previously stated, nothing in the Bird patent teaches alerting the subject by any means. Thus, the rejection to claim 5 over the Bird patent should be removed and such as requested.

The applicant's claim 6 requires, in part, that the subject is alerted to a gas flow problem audibly. As previously stated, nothing in the Bird patent teaches alerting the subject by any means. Thus, the rejection to claim 6 over the Bird patent should be removed and such as requested.

The applicant's claim 8 states that a gas flow alarm has located on an anterior surface an on off switch which is substantially flush with or below the anterior surface of the gas alarm. The purpose of the applicant's invention in claim 8 is because the

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proximal location of the gas alarm to the receiver of the gas. If the alarm on off switch feature is not located as described in claim 8 then the recipient of the gas would be more likely to accidentally disable the alarm system.

There is no disclosure in the Bird patent, nor is there any need given the device described in the Bird patent, to position the on off switch in claim 8. Thus, the rejection to claim 8 over the Bird patent should be removed and such as requested.

The applicant's claim 9 states that a second person is alerted to an interruption in gas flow by a transmitter and receiver. As the recipient of the gas is the first person and the Bird patent does not disclose alerting a first person it is not possible to alert a second person. Moreover, the Bird patent does not teach the use of a transmitter and/or receiver. Thus, the rejection to claim 9 over the Bird patent should be removed and such as requested.

Similar to claim 9 is claim 10 which states that a second person is alerted by a radio signal. As the Bird patent does not teach the use of a transmitter and/or receiver it cannot teach alerting by a radio signal. Thus, the rejection to claim 10 over the Bird patent should be removed and such as requested.

The Examiner has rejected claim 11 based on the Bird patent as lacking novelty.

However, a difference between the Bird patent and the claim 11 of the present invention is that the Bird patent does not teach a binary nasal cannula which obtains the flow of medical gas flow from a unitary conduit. The Bird patent at best teaches five conduits connected with the gas flow past the alarm system. The Bird patent presents many opportunities for leakage of the medical gas that are not present the claimed invention. The two conduits of the binary nasal cannula independently permit the medical gas to be received by the person in need of treatment. Therefore claim 11 is novel over the Bird patent.

The applicant cannot locate in the Bird patent any teaching that the gas flow alarm is set to alert a subject receiving the effluent gas. Therefore, it is believed that claim 14 is novel over the Bird patent. Thus, the rejection to claim 14 over the Bird patent should be removed and such as requested.

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The applicant's claim 15 requires, in part, that the subject is alerted to a gas flow problems by a visible light. As previously stated, nothing in the Bird patent teaches alerting the subject by any means. Thus, the rejection to claim 15 over the Bird patent should be removed and such as requested.

The applicant's claim 16 requires, in part, that the subject is alerted to a gas flow problems audibly. As previously stated, nothing in the Bird patent teaches alerting the subject by any means. Thus, the rejection to claim 16 over the Bird patent should be removed and such as requested.

The applicant's claim 18 states that a gas flow alarm has located on an anterior surface an on off feature which is substantially flush with or below the anterior surface of the gas alarm. The purpose of the applicant's claim 18 is because the proximal location of the gas alarm to the receiver of the gas. If the on off feature is not located as described in claim 18 then the recipient of the gas would be more likely to accidentally disable the alarm system. There is no disclosure in the Bird patent, nor is there any need given the device described in the Bird patent, to position the alarm on off switch in claim 18. Thus, the rejection to claim 18 over the Bird patent should be removed and such as requested.

The applicant's claim 19 states that a second person is alerted to an interruption in gas flow by a transmitter and receiver. As the recipient of the gas is the first person and the Bird patent does not disclose alerting the recipient of the gas it is not possible to alert a second person. Moreover, the Bird patent does not teach the use of a transmitter and/or receiver. Thus, the rejection to claim 19 over the Bird patent should be removed and such as requested.

Similar to claim 19 is claim 20 which states that a second person is alerted by a radio signal. As the Bird patent does not teach the use of a transmitter and/or receiver it cannot teach alerting by a radio signal. Thus, the rejection to claim 20 over the Bird patent should be removed and such as requested.

Claim 21 recites that the alarm is battery powered, again to make the warning from the alarm alert accessible to the receipt of the medical gas. The Bird patent

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teaches a device wherein intubation is required. Claim 21 recites a device that utilizes a nasal cannula. Thus, claim 21 is novel over the Bird patent and the rejection should be removed.

Regarding Claim 23 the applicant cannot locate in the Bird patent any teaching that the gas flow alarm is set to alert a subject receiving the gas. Therefore, it is believed that claim 23 is novel over the Bird patent. Thus, the rejection to claim 23 over the Bird patent should be removed and such as requested.

The applicant's claim 25 requires, in part, that the subject is alerted to a gas flow problems by a visible light. As previously stated, nothing in the Bird patent teaches alerting the subject receiving the gas by any means. Thus, the rejection to claim 25 over the Bird patent should be removed and such as requested.

The applicant's claim 27 (renumbered from 28) states that a second person is alerted to an interruption in gas flow by a transmitter and receiver. As the recipient of the gas is the first person and the Bird patent does not disclose alerting the recipient of the gas is not possible to alert a second person. Moreover, the Bird patent does not teach the use of a transmitter and/or receiver. Thus, the rejection to claim 27 over the Bird patent should be removed and such as requested.

The applicant's claim 29 (renumbered from 30) states that a gas flow alarm has located on an anterior surface an alarm reset or test feature, which is substantially flush with or below the anterior surface of the gas alarm. The purpose of the applicant's claim 29 is because the proximal location of the gas alarm to the receiver of the gas. If the alarm reset or test feature is not located as described in claim 8 then the recipient of the gas would be more likely to accidentally disable the alarm system. There is no disclosure in the Bird patent, nor is there any need given the device described in the Bird patent, to position the alarm reset or test feature in claim 29. Thus, the rejection to claim 29 over the Bird patent should be removed and such as requested.

#### Discussion of the 35 USC 103 Rejections

The Examiner has rejected claims 2, 8, 9, 10, 12, 18, 19, 20, 22, 28 (renumbered 27), and claim 29 (renumbered 28) based on Bird patent. Claims 2, 12, and 22 have

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been cancelled without prejudice and the language in these claims is now present in the respective independent claims.

The Examiner has also addressed claims 8, 18, and 30 (renumbered 29) together. The Examiner states that there is no recited advantage over the Bird patent regarding claims 8, 18, and 30 (renumbered 29). There is no requirement in United States patent law for an advantage over the cited art. The Examiner must provide reasoning as to why one skilled in the art would change the reference teachings to obtain the claimed invention.

The purpose of the applicant's claims 8, 18, and 30 (renumbered 29) is because the proximal location of the gas alarm to the receiver of the gas. If the alarm on off feature is not located as described in claims 8, 18, and 30 (renumbered 29) then the recipient of the gas would be more likely to accidentally disable the alarm system. Thus, the rejection of claims 8, 18, and 30 (renumbered 29) should be removed.

The rejection of claims 9, 10, 19, 20 and 22 are treated together by the Examiner relating to the use of a transmitter and receiver. The applicant cannot discuss this rejection as the Examiner has proved no reasoning as to why one skilled in the art would select the parameters of these dependent claims for inclusion in the respective independent claims and why such would be obvious from the Bird patent.

Claim 1 through 11 inclusive, 13 through 21 inclusive, and claims 23 through 29 inclusive are pending and reconsideration is requested, and removal, of the rejections made in the present Official Action. Should questions concerning this application arise the Examiner is urged to telephone the undersigned to advance prosecution of this application. The applicant believes the application is in condition for allowance and such is earnestly solicited. Attached hereto is a marked up version of the changes made to the specification and the claims by the current amendment. The attached sequentially numbered page(s) (is/are) entitled VERSION WITH MARKINGS TO SHOW CHANGES MADE.

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